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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,122	08/16/2001	Tony Baker	24219-001CIP2	4239
32301 7590 12/19/2006 CATALYST LAW GROUP, APC 9710 SCRANTON ROAD, SUITE S-170 SAN DIEGO, CA 92121			EXAMINER SITTON, JEHANNE SOUAYA	
			ART UNIT 1634	PAPER NUMBER
			MAIL DATE 12/19/2006	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	Application No. 09/932,122	Applicant(s) BAKER, TONY	
	Examiner Jehanne S. Sitton	Art Unit 1634	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 30 November 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☒ They raise the issue of new matter (see NOTE below);  
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attachment. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: none.  
Claim(s) objected to: 15.  
Claim(s) rejected: 1-3, 6, 7, 10-19, 22, 23, 26-39, 42 and 45-57.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
13. ☐ Other: \_\_\_\_\_.

*Attachment*

1. The proposed amendment filed 11/30/2006 will not be entered. The proposed amendment of claims 1, 17, 37, 49, 52, 54, and 56 to recite “less than about 1.25M” raises the issue of New Matter as well as issues under 112/2<sup>nd</sup> paragraph. Additionally, it is noted that this new claim limitation would require further search and consideration regarding 35 USC 102 and 103. The proposed amendment to add claims 58-63 requires further search and consideration for 35 USC 102 and 103. Additionally, the term “stabilizer” raises the issue of new matter, and the term “substantially” raises issues under 35 USC 112/2<sup>nd</sup> paragraph.

2. Arguments pertaining to the pending claims will be addressed. The response traverses the rejection under 35 USC 112/2<sup>nd</sup> paragraph and asserts that the chelator enhancing component ranges of “about 0.1M to about 1.75M”, “from about “0.5 M to about 1.50M” and “from about 0.5M to about 1.75M” does not raise the issue of New Matter because “the general rule is that a narrower range that is completely within a range that is explicitly provided in the specification can be recited in a claim”. The response cites In re Wertheim 191 U.S.P.Q. 90 (C.C.P.A 1976) and In re Blaser, 194 U.S.P.Q. 122 (C.C.P.A 1997) for support. This argument has been thoroughly reviewed but was found unpersuasive. Notably, regarding the decision for In re Wertheim, the disclosure was found to support the range of “35% to 60” because the specification had provided an example of 36%, which amounts to a 1% difference. Regarding In re Blaser, it is also noted that the specification provided an example of heating up to 80 deg. C. Therefore, applicants arguments that “To put it simply, a range that is completely encompassed by an originally filed, broader range is supported by the recitation of the originally filed range in the specification” is not found persuasive because as noted above, in each case, the specification provided an example

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which specifically supported the subrange (80 deg C) or a 1% difference (36% provided support for amendment of 25-60% to 35% - 60%). With regard to the instant application, although the range of "about 0.1M to 2M" with the preferred embodiment within of "at least 1M" is taught in the specification, the claims have been amended to recite specific subgenus ranges of "about 0.1M to about 1.75M", "from about 0.5 M to about 1.50M" and "from about 0.5M to about 1.75M" within the broader genus, which have not been disclosed, nor is it clear from the disclosure that the skilled artisan would consider 0.5M, 1.5M and 1.75 M to be supported by the recitation of a single example of 1M in the broader genus of "about .1M to 2M". Accordingly, the rejection is maintained.

3. The response traverses the rejection under 35 USC 102 over Zhang with respect to the proposed amended claims, not to the instantly pending claims and will not be considered.
4. The response traverses the rejection under 35 USC 103 over Zhang in view of Heath on the grounds that the addition of an enzyme inhibitor as taught by Heath does not remedy the deficiencies of Zhang because the inhibitor does not provide for the inactivation of non enzymatic agents, such as hemoglobin. The response further asserts that the combination of the two references would be inoperable for its intended purpose and that there is no incentive to modify the teachings of Zhang in view of Heath. These arguments have been thoroughly reviewed but were not found persuasive because the rejection was not based on the ~~any~~ assertion it would be obvious to inactivate hemoglobin by adding an enzyme inactivating reagent. The rejection was made based on the fact that given the disclosure of Zhang and Heath, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to add an enzyme inactivating component such as SDS or sarkosyl in an amount of 0.5-3% to the

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lysis buffer of Zhang because Heath specifically teaches that such components are effective to lyse cells and denature proteins. Further, the rejection did not suggest or assert that the entire reagent of Heath be used, only the SDS or sarkosyl which were well known in the art to be effective in lysis, as exemplified by the teachings of Heath. The rejection is therefore maintained.

5. The response traverses the rejection under 35 USC 103 over Zhang in view of Bertland with respect to the concentrations of the proposed claims, and will not be addressed as the claims are not pending.

6. The response traverses the rejection under 35 USC 103 over Zhang, or Sigman, or Harvey '922 or Harvey '259, each in view of Ahern on the grounds that the references fail to teach the invention in its entirety and that the comments at paragraph 17 of the office action fail to support the rejection because the fact that instructions in a kit carry no patentable weight does not lead to the conclusion that the subject matter in the kit is obvious but that the real issue is that the reagents in the kit were not shown to suppress interference by a masking agent recited. This argument has been thoroughly reviewed but was not found persuasive as the references are not required to teach the properties of the reagents for those properties to exist. Arguments regarding the proposed claim concentrations will not be addressed as they do not pertain to the instantly pending claims. The rejection is therefore maintained.

7. The response traverses the obviousness type Double patenting rejection over claims 1-8 of Baker '546 on the grounds that the remarks at paragraph 14 of the previous office action do not support the rejection because it is not accurate to state that the claimed method steps of encompass the more narrow steps of '546. This argument has been thoroughly reviewed but was

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not found persuasive as the teachings of the property of the reagents is not necessary for those properties to exist. The arguments made with regard to the concentrations of the proposed claims will not be addressed as they do not pertain to the instantly pending claims. The rejection is therefore maintained.

8. The traversals made at pages 33-34 of the response will not be addressed as they do not pertain to the instantly pending claims.

9. At page 35, the response traverses the obviousness type double patenting rejections over the '543 application as well as the '543 application in view of Ahern on the grounds that there is no teaching or suggestion of the suppression of the specific masking agents. This argument has been thoroughly reviewed but was not found persuasive because the teachings of the property of the reagents is not necessary for those properties to exist. Arguments made with regard to the proposed amended claims will not be addressed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

*Jehanne S. H.*

Jehanne Sitton  
Primary Examiner  
Art Unit 1634

*12/14/06*